Kill-Step Validation of the Baking Process to comply with FSMA rule

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Outline

- Introduction
- FDA’s FSMA validation requirement
- Baking Kill-Step validation (KSV) research
- Foundational KSV research: Hamburger buns
- Baking Process Kill-Step Calculators
- Additional KSV research
- Benefits of KSV research
Introduction

- In the United States:
  - 2,800 commercial bakeries
  - 6,000 retail bakeries
  - Market value = $30 billion

- Safe production record compared to the rest of the food industry

- Yet, there were 4,200 illnesses related to bakery products from 1998 to 2007
Bakery Products: Food Safety Challenges?

- *Salmonella spp.* in bakery ingredients and products could create a public health risk if the product is improperly baked
- *Salmonella* can survive in adverse conditions
- Pathogens such as *Salmonella spp.* can be introduced into bakery products through a wide range of ingredients:
  - Egg
  - Milk products
  - Flour
  - Milk chocolate
  - Coconut
  - Peanut butter
  - Fruit
  - Spices
  - Yeast flavorings
The need...

- Most bakery products undergo a **putative kill step** at the point of production, such as baking or cooking.

- However, these lacks **scientific proof or validation**.

- **FDA-FSMA** regulatory requirement requires validation and verification of kill-step.
The three key FSMA requirements are:

1. Validation of preventive controls
2. Provide scientific evidence
3. Keep documents/records accessible for FDA inspection
Kill-step validation research to help the baking industries

- AIB International has partnered with industry stakeholders & various state universities to develop kill-step validation (KSV) procedures for various bakery products.

Main objectives:
- Develop KSV procedures for bakery products
- Publish KSV research findings for the benefit of bakery industry’s food safety needs
- Develop Baking Process Kill-Step Calculators
- Provide on-site support and training for the US baking industry to comply the FDA-FSMA’s (117.160) validation and verification requirement
Baking Process Kill-Step Validation Research Collaborators

American Bakers Association
The ABA - FTRAC

Kansas State University

AIB INTERNATIONAL
Since 1919

The University of Georgia

FTRAC: Food Technical and Regulatory Affairs Committee
Validation of baking as a kill step in controlling *Salmonella* in hamburger buns
Research objectives

1. Validate the baking process as a kill step in reducing *Salmonella* spp. during hamburger bun manufacturing

2. Validate the baking step’s effectiveness in reducing *S. cerevisiae* and *E. faecium* to determine appropriateness of utilizing non-pathogenic surrogate for industry validation and process verification purposes

3. Determine the heat resistance *viz.* D-value, and *z*-value of *Salmonella* spp., *S. cerevisiae* and *E. faecium* in hamburger bun dough
Materials and methods
Bun baking temperature and sampling

- **Baking temperatures:** 425 ºF (218 ºC)
- **Time:** 9, 11, 13, and 13 + 30 minute cooling phase
- **Initial microbial** (*Salmonella* or *Enterococcus*) concentration of ~6/7 log was maintained in the flour and dough
- After both proofing and baking, the bacterial concentration was determined to confirm a minimum of 5 log kill
- Surviving *Salmonella* or *Enterococcus* were enumerated using selective & injury-recovery media
- The experiment was replicated three times
Microorganisms used in this research

- **Salmonella** serovars:
  - *Salmonella enterica* serovar Typhimurium (ATCC 14028)
  - *Salmonella enterica* serovar Newport (ATCC 6962)
  - *Salmonella enterica* serovar Senftenberg (ATCC 43845)

- **Enterococcus**:
  - *Enterococcus faecium* (ATCC 8459)

- **Yeast**:
  - *Saccharomyces cerevisiae* (Fleischmann’s compressed yeast)
Hamburger bun kill-step validation research

1. Salmonella spp.
2. Enterococcus spp.
3. Hamburger bun kill-step validation research
4. 
5. 
6. 
7. Salmonella spp.
8. Enterococcus spp.
Results

Figure 1. Survival population of *Salmonella* serovars, *Enterococcus faecium* and *Saccharomyces cerevisiae*, in hamburger buns during baking at 218°C (using selective media)

Enumerated on selective media; xylose lysine deoxycholate agar, m-*Enterococcus* agar and potato dextrose agar.

Figure 2. Survival population of *Salmonella* serovars, *Enterococcus faecium* and *Saccharomyces cerevisiae*, in hamburger buns during baking at 218°C (using injury recover media)
# Microbial kinetics study

## Table 1. D-values (min) and z-values (°C) of a 3-strain *Salmonella* spp. cocktail, and *Enterococcus faecium* ATCC 8459 in hamburger bun dough

<table>
<thead>
<tr>
<th>Temperature (°C)</th>
<th><em>Salmonella</em> spp.</th>
<th><em>E. faecium</em></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BHI/XLD&lt;sup&gt;a&lt;/sup&gt;</td>
<td>XLD&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>55</td>
<td>28.64 ± 5.19</td>
<td>21.30 ± 2.61</td>
</tr>
<tr>
<td>58</td>
<td>7.61 ± 0.61</td>
<td>7.53 ± 0.61</td>
</tr>
<tr>
<td>61</td>
<td>3.14 ± 0.32</td>
<td>2.29 ± 0.21</td>
</tr>
<tr>
<td>z-value</td>
<td>6.68 ± 0.94</td>
<td>6.22 ± 0.32</td>
</tr>
</tbody>
</table>

*Salmonella* cocktail: *S. enterica* serovar Typhimurium (ATCC 14028); *S. enterica* serovar Newport (ATCC 6962); *S. enterica* serovar Senftenberg (ATCC 43845).

<sup>a</sup> Injury-recovery media, Brain Heart Infusion (BHI) agar with Xylose Lysine Desoxycholate (XLD) agar overlay;  
<sup>b</sup> Selective medium, XLD agar;  
<sup>c</sup> Injury-recovery media, BHI agar with m-Enterococcus (mE) agar overlay;  
<sup>d</sup> Selective medium, mE agar
Table 2. D-values (min) and z-value (°C) of *Saccharomyces cerevisiae* in hamburger bun dough

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Bun dough</th>
</tr>
</thead>
<tbody>
<tr>
<td>52</td>
<td>18.73 ± 0.72</td>
</tr>
<tr>
<td>55</td>
<td>5.67 ± 1.51</td>
</tr>
<tr>
<td>58</td>
<td>1.03 ± 0.21</td>
</tr>
<tr>
<td>z-value</td>
<td>4.74 ± 0.34</td>
</tr>
</tbody>
</table>

Note: The temperature for yeast studies were decreased due to the fact that *Saccharomyces* is completely dead at 61 °C instantaneously.

Media: Potato dextrose agar supplemented with 100 ppm of chloramphenicol
Figure 3. Mean internal temperature profile of hamburger buns during baking at 218°C oven temperature for 13 min followed by 30 min of cooling.
First scientific research demonstrating validation and thermal resistance of *Salmonella*, *E. faecium* and yeast in a bakery product

*Journal of Food Protection*, 79: 544-552 (2016)
The FDA had positive comments on
- AIB’s intent to design kill-step validation (KSV) procedure, and KSV calculators for various bakery products
- Provide on-site support, and
- Training for the US baking industry

Bakery products selected for the KSV-Gen 2 and 3 are appropriate

Interaction with the FDA will continue during next generation bakery product validation studies
Additional bakery product validation research

- There are > 2,000 bakery products in the market.
- Bacteria respond/behaves differently at varying moisture levels, pH, fat content, etc.
  - *Salmonella* has shown the highest resistance in low water activity and high fat foods.
- Additional research is needed for baked goods with varied moisture contents, pH, water activities ($a_w$), etc.
- Publish the next generation baking validation research findings, thus providing documentary evidence for the benefit of bakery industry’s food safety needs.
Baking Process Kill-Step Calculator

Translation of research to commercial application
Baking Process Kill-Step Calculator

Objective:

To provide bakery manufacturers with a science-based validation tool that can be used to demonstrate the effectiveness of a baking process to destroy *Salmonella* spp. in a variety of bakery products.
Baking Process Kill-Step Calculator (BPKC)

How Does It Works?
**How it Works?**

- **D, Z and T-ref** are obtained from AIB’s KSV study
- Temp data obtained from data logger


**T-ref: Reference Temperature**

- **D-Value:** This indicates time in minutes at a constant temperature, that is necessary to destroy 90% or 1 log of the organism present at a given reference temperature.
- **z-Value:** This is the temperature increase required to reduce the thermal death time by a factor of 10.
BPKC: How It Works?

- Download the calculator to your computer from AIB's website

- Format the temperature profile (time-temperature data) so that the time is in intervals of 15 seconds and the temperature is in °F or °C

- Once programmed, the temperature data logger is placed in the cold spot of an oven, the probes are inserted into the geometric center of the to-be baked products (e.g., dough)

- Let the data logger continue to travel through the coolest oven zone, and retrieve after the baking cycle is complete

- The process is repeated five times
Download the temperature profile (time-temperature data) from the data logger to an Excel sheet

Select 20 data points from the probe that takes the longest time to reach 170°F (77°C) to plug into the Kill-Step calculator to calculate total process lethality
Output Cont.

- Determines $F$ - value and cumulative $F$ - value
- Automatically determines the total process lethality (e.g. 5 log) for *Salmonella*
- Generates three graphs: Product internal temperature, $F$ - value/min and cumulative log reductions
If the desired log reduction is achieved for the baking process, the process lethality report generated can be used as a supporting documentation for FSMA validation and verification process.

**Baking Process Kill-step Calculator:**

Output in terms of *Salmonella* log reductions
AIBI has released “Baking Process Lethality Calculators” for:

- Hamburger buns,
- 100% whole wheat multi-grain pan bread
- Basic round top cake muffins
- Crisp cookies
- Soft cookies

These Kill Step calculators can be downloaded from AIBI’s website for free and comes with complete instructions and procedures.

We strongly believe that the baking process Kill-Step calculators will enable bakeries of all sizes to meet requirements of the FDA FSMA without investing in costly and time-consuming microbial challenge studies.
Benefits of Kill-Step Validation Research

- Pathogen free bakery products assuring maximum safety
- Protects consumers, builds confidence
- Demonstrates FSMA compliance
- Can save bakery industries millions of dollars by avoiding repetition and duplication of KSV research
Acknowledgements

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- Prof. George Milliken, emeritus professor of statistics, Kansas State University, Manhattan, KS
References

Questions?

Thank you